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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/812,250
Filing Date: March 29, 2004
Appellant(s): CHAMBERS, JEFFREY W.

Timothy Czaja
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/19/09 appealing from the Office action mailed 9/19/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,458,151	Saltiel	10-2002
2002/68866	Zikorus et al.	6-2002
5,749,890	Shaknovich	5-1998

6,532,380

Close et al.

3-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 28-30,32,34-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saltiel (6458151) in view of Zikorus et al. (2002/68866). Saltiel discloses a method of deploying a stent within a patient adjacent the ostium using a deployment site locator, abstract. Saltiel discloses a distal end of a guide catheter is used to deliver an expandable site locator **20** to a position adjacent the ostium, col. 4, lines 25-33. Saltiel additionally discloses deploying the stent at the desired location once the site locator is expanded and contacts bodily structures immediate the ostium, col. 6 lines 13-16. The stent is then delivered to the desired location at the ostium (col. 6, lines 29-31) and then the site locator is removed from the patient, col. 6, lines 35-40. The use of "fixed relative to" and "fixed distance" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. Thus, since the stent is positioned adjacent to, it at a "fixed position" relative to the site locator. Regarding claim 30, the adjustment of the stent to place it is done by visual indication, col. 2, lines 39-43. With respect to claim 32, Saltiel does disclose if radiopaque techniques are used for deployment, the deployment site locator and stent have radio-opaque markers used, col. 6, lines 24-26. Regarding claim 35, Saltiel additionally discloses a guidewire can be used such that the guide catheter can be delivered over the guidewire, col. 5, lines 37-39,55-59. However, Saltiel fails to disclose deploying the site locator having a plurality of rods to the location to be treated. Zikorus

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shows the end of a catheter adjacent an ostium of a vessel, Fig. 3 and teaches delivering the catheter as such, abstract, paragraph 10. A deployment site locator **56** is delivered through the catheter and includes a plurality of rods **58**. Zikorus teaches the site locator with the rods provides an alternative means such as sensors for detecting contact with a vessel wall (paragraphs 43,48) to determine a vessel location without using large ultrasound or other similar imaging equipment, paragraph 8. Zikorus shows (Figs. 6-9,11) a side view of the site locator with a base **106** and how (paragraph 27) the rods expand relative to one another to a maximum dimension. Zikorus et al. also teaches the site locator provides feedback such that a position of the ostium is determined by contacting vessel walls, paragraphs 11,15,29. It would have been obvious to one of ordinary skill in the art to use an alternative site detection means that expands having rods as taught by Zikorus et al. in the method of Saltiel to accurately deliver a stent to a location adjacent the ostium with the ability to give feedback to the surgeon. Regarding claim 36, the stent would be delivered over the guidewire and through the deployment site locator of Zikorus as seen in Fig. 8. With respect to claims 40,43-45 since the rods are designed to deflect outward, it can be construed that they have a spring action and the rods have a length such that the intermediate section would engage a portion of the proximal ostium, see Fig. 6a showing the flaring out of which defines a maximum outer dimension that is greater than the ostium opening. Self-expanding material that display this property is well known in the art. Regarding claim 42, since Saltiel discloses (col. 5, lines 59-61) the stent is located "distal" to the

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vessel where it is to be deployed, it is not being considered to be placed in the target vessel until the rods are extended and the ostium location is determined.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saltiel (6458151) in view of Zikorus et al. (2002/68866) as applied to claim 30 above, and further in view of Close et al. (6532380). Saltiel as modified by Zikorus et al. is explained above. It is noted that Saltiel discloses visual indication is used to position the stent and that radiographic techniques or modalities are used, col. 6, lines 24-30. However, Saltiel in view of Zikorus do not state that x-ray imaging is used for adjusting the position of the stent. Close et al. teach that x-ray imaging is used in placement of a stent, col. 3, lines 62-67, col. 6, lines 33-36. It would have been obvious to one of ordinary skill in the art to use x-ray imaging as taught by Close et al. in the method of positioning a stent at an ostium disclosed by Saltiel and modified in view of Zikorus et al. such that an accurate placement can be achieved and known by the surgeon by the results given by the x-ray.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saltiel (6458151) in view of Zikorus et al. (2002/68866) as applied to claim 28 above, and further in view of Shaknovich (5749890). Saltiel as modified by Zikorus et al. is explained above. It is noted that Saltiel discloses the aorta may be a location where the positioning of the stent is performed near, col. 1. However, Saltiel in view of Zikorus do not explicitly state the coronary artery and the aorta wall is of the ostium where the position of the stent is done. Shaknovich teaches that the target vessel to be stented is the coronary artery and the vascular structure proximate the ostium is the aorta wall,

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col. 6, lines 27-29,41-44. It would have been obvious to one of ordinary skill in the art to surgically implant a stent in the ostium near the aorta wall as taught by Shaknovich using the method of positioning a stent at an ostium disclosed by Saltiel and modified in view of Zikorus et al. such that a lesion in this region is treated.

(10) Response to Argument

I: Response to argument of the rejection of (6458151) in view of Zikorus et al. (2002/68866). Applicant states that Zikorus does not disclose the catheter device includes a deployment site locator and is used for a different purpose. First, it should be noted that the apparatus of Zikorus' device is clearly used to determine a position of the ostium prior to performing a procedure, paragraphs 11,13,26,38 and 48 of which sensors can even be used with the electrode rods such that upon contact it gives feedback to the surgeon as to the location of the catheter. Applicant additionally contends the hook-shaped guide wire structure of Zikorus' apparatus cannot be considered "part" of the rods. However, the Examiner respectfully disagrees since the hook shaped guide wire is clearly an elongate solid structure and since Applicant has not set forth any special definition of how exactly the rods are "affixed" to the base, it can be interpreted to be "part" of the rods. The claim (28) does not require all rods to be directly affixed to the base or even how the base is coupled with the catheter when assembled for delivery. Thus, an indirect coupling of the wire rod with the base is within the scope of the claim since the wire is assembled with the catheter and the base structure including the rods. Applicant also states the claimed method is different in the way that it operates from Zikorus's structure by relying on the limitation "with at least

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one of the plurality of rods and the deployment site locator in the expanded state”.

However, it should be noted that this recitation can be interpreted such that it only requires one at a minimum of any rods in the structure to be expanded. Thus, even if the hook shaped wire that can engage the ostium does not flare out or “expand”, there is an electrode rod that is expanded or flared out for ostium detection by having sensors thereon, see paragraphs 43,48. As mentioned above, the rods or electrodes of Zikorus’ apparatus collectively define a maximum outer dimension when expanded that is greater than a maximum dimension of the ostium and in combination with the wire aid in detecting the ostium prior to deployment. Thus, it would be obvious in view of Zikorus to use the teaching of electrode rods to detect the ostium and have them contact bodily structures to determine the position of the ostium for use in the method of Saltiel to deliver a stent and provide feedback to the surgeon through the use of site locator. In conclusion the fact that the structures of Zikorus’ apparatus performs additional functions that are not claimed is irrelevant because the electrode rods and the guide wire taught by Zikorus together teach the claimed method of detecting the ostium position prior to performing a procedure. Therefore the plurality of rods as a site locator taught by Zikorus clearly can be utilized with the method and apparatus of Saltiel.

II. Rejection of claim 31 over Saltiel in view of Zikorus and further in view of Close. Applicant provides no argument with respect to this rejection except that Saltiel and Zikorus fail to disclose the invention and thus claim 31 is not obvious over the proposed rejection. It appears that the comments were mistaken and should have been to Close and not Shakhovich. This is not persuasive and cannot overcome the rejection

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because they do not clearly point out the patentable novelty which he thinks the claims present in view of the state of the art disclosed by the references cited. Further, they do not show how the claim avoids these references combined.

II. Rejection of claim 33 over Saltiel in view of Zikorus and further in view of Shakhovich. Applicant provides no argument with respect to this rejection except that Saltiel and Zikorus fail to disclose the invention and thus claim 33 is not obvious over the proposed rejection. This is not persuasive and cannot overcome the rejection because they do not clearly point out the patentable novelty which he thinks the claims present in view of the state of the art disclosed by the references cited. Further, they do not show how the claim avoids these references combined.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Brian E Pellegrino/

Primary Examiner, Art Unit 3738

McDermott/

Conferees:

/Corrine M

Supervisory

Patent Examiner,

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